SECTION 5 - 510(K) SUMMARY

AVIAFIT™ DEVICE

510(k) Number K 071744

SEP 25 2007

Applicant's Name:

Company name:	FlowMedic Ltd.
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Tel.:	+972 (4) 627-5559
Fax:	+972 (4) 627-5560
E-mail:	info@flowmedic.com

Contact Person:

Contact Name:	Ahava Stein
Company:	A. Stein – Regulatory Affairs Consulting
Address:	20 Hata'as St. (P.O.B. 124) Kfar Saba 44425 ISRAEL
Tel.:	+972 (9) 7670002
Fax.:	+972 (9) 7668534
E-mail:	asteinra@netvision.net.il

Date Prepared:

Date: June 20, 2007

Name of the device:

AviaFit™ Pulsating Legband

Trade or proprietary name, if applicable:

AviaFit™ Pulsating Legband

Common or usual name:

Compressible Limb Sleeve

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 25 2007

FlowMedic Ltd.
c/o Ms. Ahava Stein
Regulatory Affairs Consulting Ltd.
Beit Hapaamon Suite 102
20 HATAAS Str. (P.O.B 124)
Kfar Saba
44425
Israel

Re: K071744
AviaFit™ Device
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II (two)
Product Code: JOW
Dated: September 2, 2007
Received: September 7, 2007

Dear Ms. Stein:

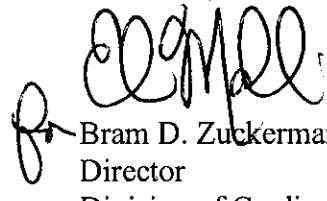
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4 - INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K071744

Device Name: AviaFit™ Device

Indications for use: The Aviafit™ is intended to improve blood circulation in the lower limbs and reduce the risk of deep vein thrombosis, edema and leg discomfort during limited mobility conditions at home, at the office and during mid-long haul flights.

Prescription Use _____ (Per 21 C.F.R. 801 Subpart D)

OR

Over-The-Counter Use √ (Optional Format Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K071744